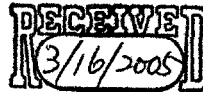


*The Solae[®]
Company*



Solae, LLC
P.O. Box 88940
St. Louis, MO 63188 USA
800.325.7108

VIA AIRBORNE EXPRESS

March 10, 2005

Shellee Anderson
Team Leader
Nutrition Policy and Labeling Staff
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety
Department of Health and Human Services
Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: 2004Q-0151 Qualified Health Claim (QHC): Soy Protein and Cancer

Dear Ms. Anderson:

This letter responds to the comments dated January 24, 2005, submitted by The Westin A. Price Foundation concerning the Qualified Health Claim (QHC): Soy Protein and Cancer petition submitted by Solae, LLC (hereafter "Solae").

The January 24, 2005 comments do not add any new information. Both, the information previously provided by The Solae Company and the Health Claim for Soy Protein and Coronary Heart Disease approved by the FDA in 1999 address the issues raised in by The Westin A. Price Foundation.

The Solae Company remains confident in the scientific methodology and evidence supporting our Petition. There have been many epidemiological studies, particularly in recent years, which have examined the relationship between soyfoods consumption and the risk of various cancers in humans. The Solae Company has analyzed these studies independently and has conducted a meta-analysis. In addition, five independent researchers reviewed the studies and have concluded that the totality of the publicly available scientific evidence supports the substance/disease relationship that consumption of soy protein-

2004Q-0151

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Shellee Anderson
March 10, 2005
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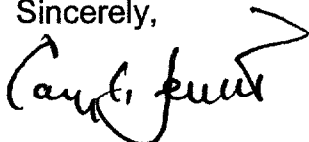
containing foods is related to a lower risk of certain cancers. The evidence is particularly strong for cancers of the breast, prostate, and gastro-intestinal tract. The Solae Company was particularly startled by The Westin A. Price Foundation's position that soy protein is not safe and lawful.

A strong administrative record, based on a full and complete review of all relevant science, fully supports FDA's determination that soy protein is an appropriate subject for a health claim for reduced risk of heart disease. In the Final Rule, Food Labeling: Health Claims: Soy Protein and Coronary Heart Disease (64 FR 57700), FDA addressed numerous comments on safety of soy protein, including safety of soy protein-based infant formulas, potential effects of lysinoalanine, potential effects of nitrates and subsequent nitrosamine formation, potential effects of trypsin inhibitors, potential effects of phytic acid on mineral balance, potential effects of soy isoflavones (estrogenic effects, fertility effects, developmental effects, and goitrogenic effects), and concerns on allergenicity to soy protein. FDA responded to all these concerns and concluded soy protein to be safe and lawful.

We appreciate the opportunity to comment. The scientific data overwhelmingly supports that a relationship does exist between consumption of soy protein and a reduction in risk of certain cancers. As indicated above, many of the studies cited by The Westin A. Price Foundation are already addressed in The Solae Company's petition.

Please do not hesitate to contact us if you require any further information.

Sincerely,

A handwritten signature in black ink, appearing to read "Cary A. Levitt", with a stylized flourish extending from the end.

Cary A. Levitt
Vice President and General Counsel

cc: Dr. Gregory Paul
Geri Berdak
Tony Arnold